MAY 0 2 2002

9. 510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of safety and effectiveness information is being submitted in accordance with the requirements of The Safety Medical Devices Act of 1990 (SMDA 1990) and 21 CFR Part 807.92.

Assigned 510(k) Number: K020758

Date of Summary Preparation: February 15, 2002

Distributor:
Pharmacia
Diagnostics Division, US Operation
7425-248-1
7000 Portage Road
Kalamazoo, MI 49001

Manufacturer:
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Device Name: Varelisa® Cardiolipin IgM Antibodies

Common Name: Cardiolipin autoantibody immunological test system

Classification:

Product Name	**Product Code**	**Class**	**CFR**
Varelisa® Cardiolipin IgM Antibodies	82MID	II	866.5560

Substantial Equivalence to:

Varelisa® Cardiolipin (IgM) Antibodies

Intended Use Statement

The Varelisa Cardiolipin IgM Antibodies EIA kit is designed for the semiquantitative and qualitative determination of IgM antibodies against cardiolipin in serum or plasma to aid in the diagnosis of antiphospholipid syndrome (APS) and to evaluate the thrombotic risk in patients with systemic lupus erythematosus (SLE).

General Description of the Device

The Varelisa Cardiolipin IgM Antibodies is an indirect noncompetitive enzyme immunoassay for the semiquantitative and qualitative determination of IgM antibodies against cardiolipin in serum or plasma.

Anti-cardiolipin antibodies (aCL) belong to the group of anti-phospholipid antibodies (aPL). aCL are considered to be of significant diagnostic relevance, as a correlation has been found between these antibodies and a tendency towards thromboses. This results in an increased incidence of venous/arterial thromboses (including apoplexy), thrombocytopenia, livedo reticularis, habitual abortion and neurological manifestations in aCL/LA-positive patients. Elevated levels of aCL may also be found in patients with cerebrovascular insufficiency or myocardial infarction. aPL play a direct role in the pathogenesis of APS.

Varelisa® Cardiolipin IgM Antibodies Test Principle

Varelisa Cardiolipin IgM Antibodies is an indirect noncompetitive enzyme immunoassay for the semiquantitative and qualitative determination of cardiolipin IgM antibodies in human serum or plasma. The wells of a microplate are coated with bovine cardiolipin antigen. Antibodies specific for cardiolipin present in the patient sample bind to the antigen.

In a second step an enzyme labeled second antibody (Conjugate) binds to the antigen-antibody complex which leads to the formation of an enzyme labeled antigen-antibody sandwich complex.

The enzyme labeled antigen-antibody complex converts the added substrate to form a colored solution. The rate of color formation from the chromogen is a function of the amount of Conjugate complexed with the bound antibody and thus is proportional to the initial concentration of the respective antibodies in the patient sample.

Device Comparison

Varelisa Cardiolipin (IgM) Antibodies (the original/predicate device) and Varelisa Cardiolipin IgM Antibodies (the new/modified device) both are indirect noncompetitive enzyme immunoassays for semiquantitative and qualitative determination of IgM antibodies against Cardiolipin in serum or plasma.

Based on currently available data from the literature the measuring of these antibodies not only provides aid in the evaluation of the thrombotic risk in patients with systemic lupus erythematosus, but also aids in the diagnosis of the antiphospholipid syndrome (APS). Thus the intended use of Varelisa Cardiolipin IgM Antibodies was adapted to the current state of scientific knowledge.

The essential differences between both assays are the new choice of antigen supplier and a changed blocking procedure.

Important common features between old and new version are the nature of the antigen determining the specificity of the assay, Bovine Cardiolipin, and the presence of β2-glycoprotein I in the blocking buffer.

Laboratory equivalence

The comparability of the new and the old version Varelisa Cardiolipin IgM Antibodies is supported by a data set including

- results obtained within a comparison study analyzing positive, equivocal and negative sera
- results obtained for externally defined Calibrators
- results obtained for samples from apparently healthy subjects (normal population)

The data show that the assay performs as expected from the medical literature. Differing results are probably due to the changed blocking procedure.

In summary, all available data support that the new/modified device, Varelisa Cardiolipin IgM Antibodies Assay is substantially equivalent to the predicate/original device, Varelisa Cardiolipin (IgM) Antibodies Assay, and that the new/modified device performs according to state-of-the-art expectations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Michael Linss, Ph.D.
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Freiburg
GERMANY

MAY 02 2002

Re: k020758
Trade/Device Name: Varelisa® Cardiolipin IgM Antibodies
Regulation Number: 21 CFR 866.5660
Regulation Name: Multiple Autoantibodies Immunological Test Sytem
Regulatory Class: II
Product Code: MID
Dated: March 6, 2002
Received: March 7, 2002

Dear Dr. Linss:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Varelisa® Cardiolipin IgM Antibodies- Device Modification
510(k) Submission
Section 1. Indications for Use Statement

510(k) Number: K020758

Device Name: **Varelisa® Cardiolipin IgM Antibodies**

Intended Use Statement

The Varelisa Cardiolipin IgM Antibodies EIA kit is designed for the semiquantitative and qualitative determination of IgM antibodies against cardiolipin in serum or plasma to aid in the diagnosis of antiphospholipid syndrome (APS) and to evaluate the thrombotic risk in patients with systemic lupus erythematosus (SLE).

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020758